JUN 1 2 2013

510(k) Summary

NAME OF SPONSOR:

Ortho Development Corporation
12187 South Business Park Drive
Draper, Utah 84020

510(k) CONTACT:

Tom Haueter
Regulatory Affairs Manager
Telephone: (801) 553-9991
Facsimile: (801) 553-9993
Email: thaueter@orthodevelopment.com

DATE PREPARED:

July 11, 2012

PROPRIETARY NAME:

Vusion® CS Plus

COMMON NAME:

Intervertebral Body Fusion Device

CLASSIFICATION:

21 CFR 888.3080, Intervertebral Body Fusion Device.

DEVICE PRODUCT CODE:

ODP

PREDICATE DEVICES:

LDR Spine Cervical Interbody Fusion System (K091088)
LDR Spine

ROI-C Cervical Cage (K113559)
LDR Spine

Aesculap CeSpace PEEK Spinal Implant System (K083311)
Aesculap® Implant Systems

Aleutian IBF System (K113138)
K2M, Inc.

Crystal™ Intervertebral Body Fusion Device (K073351)
Spinal Elements

DEVICE DESCRIPTION:

The Vusion® CS Plus system is designed for cervical intervertebral body fusion. The implant is a non-sterile PEEK Optima LT1 (ASTM F2026) implant body and two tantalum (ASTM F560) marker pins and is provided in multiple footprints, lordotic angles, and heights to match patient's anatomy. The implant includes machined

ORTHO DEVELOPMENT®

fixation teeth on the superior and inferior surfaces, a graft window passing between the superior and inferior surfaces, and an insertion hole for implant placement .

INTENDED USE:

The Vusion® CS Plus device is intended for spinal fusion procedures at one level (C2-T1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone.

This device is intended to be used with a supplemental internal fixation system appropriate for use in the cervical spine. .
This device is intended to be used in patients who have had six weeks of non-operative treatment.

TECHNOLOGICAL CHARACTERISTICS:

Vusion® CS Plus has the same technological characteristics as the predicate devices. These include:

- Intended use (as described above)
- Basic design
- Material (PEEK)
- Sizes (widths, lengths, heights are within range(s) offered by the predicate systems)

Therefore the fundamental scientific technology of Vusion® CS Plus is the same as previously cleared devices.

PERFORMANCE DATA:

The following non-clinical mechanical tests were conducted on the worst case configurations of Vusion® CS Plus:

- Static and dynamic compression testing per ASTM F2077
- Static shear testing per ASTM F2077
- Static and dynamic torsion testing per ASTM F2077
- Subsidence testing per ASTM F2267

The mechanical test results demonstrate that Vusion® CS Plus devices perform as well as or better than the predicate devices. Therefore, Vusion® CS Plus is as safe and effective as the predicates.

CONCLUSIONS:

Based on similarities in intended use, design, materials, manufacturing methods, and packaging, Vusion® CS Plus is substantially equivalent to the previously cleared predicate devices. Mechanical test results demonstrate that the proposed Vusion® CS Plus is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Letter Dated: June 12, 2013

Ortho Development Corporation
% Mr. Tom Haueter
Regulatory Affairs Manager
12187 South Business Park Drive
Draper, Utah 84020

Re: K122588
Trade/Device Name: Vusion® CS Plus
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: May 28, 2013
Received: May 29, 2013

Dear Mr. Haueter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

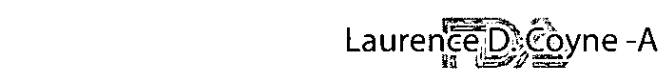
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122588

Device Name: Ortho Development **Vusion® CS Plus**

Indications for Use:

The Vusion® CS Plus device is intended for spinal fusion procedures at one level (C2-T1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone.

This device is intended to be used with a supplemental internal fixation system appropriate for use in the cervical spine.

This device is intended to be used in patients who have had six weeks of non-operative treatment.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices